APPENDIX TO GOVERNMENT'S TRIAL BRIEF

This Appendix provides an overview of: (1) the federal Medicare and Medicaid programs; (2) Specific provisions of the Social Security Act dealing with special shoes for Medicare beneficiaries who suffer from certain effects of diabetes; (3) Texas State laws regarding licensing and regulating persons practicing orthotics and orthotic facilities; and (4) a glossary of common terms and acronyms, and definitions relevant to this case.

(1) MEDICARE is a health care benefit program signed into law on July 30, 1965 in Title XVIII of the Social Security Act (42 U.S.C. § 1395j). It pays for specified medical benefits, items, and services for people age 65 or older, people under age 65 with certain disabilities, and people of all ages with permanent kidney failure requiring dialysis or a kidney transplant (End-Stage Renal Disease). The federal government is responsible for administering and funding the program. Medicare is a health care benefit program under 18 U.S.C .§ 1347.

(2) MEDICAID is a health care benefit program signed into law on July 30, 1965 in Title XIX of the Social Security Act (42 U.S.C. § 1396 *et seq*). It pays for specified medical benefits, items, and services for qualified persons who have limited income; who are pregnant; and persons with certain disabilities who fit into an eligibility group that is recognized by federal and state law. The program is funded and administered jointly by the federal government and by the states. The federal financial participation (FFP) or grant to the states for Medicaid under 42 U.S.C. §§1396, 1396a, and 1396b(a) is subject to change every October 1, but the federal share is usually approximately 60% of the amount of each state's total Medicaid budget. State funds comprise the remainder. The federal government exercises considerable oversight of the states' Medicaid programs and their spending of the federal grants.

Medicaid is a health care benefit program under 18 U.S.C. § 1347.

(3) CROSS OVER CLAIMS Medicare will generally pay 80 percent of the allowed amount of covered medical benefits, items, or services for individuals who qualify under Medicare Part B. Most secondary insurers will help pay the other 20 percent. Medicaid is considered a secondary payor if the Medicare beneficiary is also a Medicaid beneficiary. In those situations, claims to Medicaid for payment of the remaining 20 percent are called cross-over claims. Cross-over claims to Medicaid are valid only when the underlying Medicare claims are valid.

(4) MEDICARE PAYMENTS FOR SPECIAL SHOES Medicare/Medicaid covers the cost of special shoes for patients with diabetes so long as the shoes are "custom-molded" shoes with inserts or "extra-depth shoes" with inserts (sometimes called depth shoes or diabetic shoes) **and**, when all three of the following conditions of 42 U.S.C. § 1395x(s)(12)(A), (B), and (C) are met.

"(A) the physician who is managing the individual's diabetic condition

(I) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre- ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and

(ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;

(B) the particular type of shoes are prescribed by a podiatrist, other qualified physician (as established by the Secretary [of the U.S. Health and Human Services]) ; and

(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary [of the US Health and Human Services]) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area."

"Off-the-shelf" shoes are not "custom molded" or "extra depth" shoes.

Medicaid does not pay for "custom-molded" shoes with inserts or "extra-depth shoes" with inserts for adult Medicaid beneficiaries unless Medicare is the first payor on the claim. Medicaid will then pay the remainder of the allowed charge as a cross-over claim.

(5) DEFINITIONS OF "EXTRA-DEPTH SHOES" WITH INSERTS and "CUSTOM-MOLDED" SHOES WITH INSERTS

As mandated by law only "extra-depth shoes" with inserts (sometimes called depth shoes) and "custom-molded" shoes with inserts are covered by Medicare. Those terms and other terms pertaining to them are defined by Medicare as follows:

DEPTH OR EXTRA DEPTH SHOES means shoes that:

a) Have a full length, heel-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts;

b) Are made from leather or other suitable material of equal quality;

c) Have some form of shoe closure; and

d) Are available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoes according to

the American standard last sizing schedule or its equivalent. (The American standard last sizing schedule is the numerical shoe sizing system used for shoes sold in the United States.) (See CMS *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, Quality Standards,* Appendix C. Definition of Terms)[1]

CUSTOM-MOLDED SHOES means shoes that:

a) Are constructed over a positive model of the patient's foot;

b) Are made from leather or other suitable material of equal quality;

c) Have removable inserts that can be altered or replaced as the patient's condition warrants; and

d) Have some form of shoe closure. (See CMS *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, Quality Standards,* Appendix C. Definition of Terms)

INSERTS means total contact, multiple density, removable inlays that are directly molded to the patient's foot or a model of the patient's foot and that are made of a suitable material with regard to the patient's condition. (See CMS *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, Quality Standards,* Appendix C. Definition of Terms)

MOLDED-TO-PATIENT-MODEL means a particular type of custom fabricated device in which either:

a) An impression (usually by means of a plaster, or fiberglass cast) of the specific body part is made directly on the patient, and this impression is then used to make

[1] www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandards.pdf

a positive model of the body part from which the final product is crafted; or

b) A digital image of the patient's body part is made using computer-aided design-computer aided manufacturing (CAD-CAM) systems software. This technology includes specialized probes/digitizers and scanners that create a computerized positive model and then direct milling equipment to carve a positive model. The device is then individually fabricated and molded over the positive model of the patient. (See CMS *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, Quality Standards,* Appendix C. Definition of Terms)

POSITIVE MODEL OF THE PATIENT means:

a) Molded to patient model is a negative impression taken of the patient's body member and a positive model rectification is constructed; or

b) CAD-CAM system, by use of digitizers, transmits surface contour data to software that the practitioner uses to rectify or modify the model on the computer screen. The data depicting the modified shape is electronically transmitted to a commercial milling machine that carves the rectified model; or

c) Direct formed model is one in which the patient serves as the positive model. The device is constructed over the model of the patient and is then fabricated to the patient. The completed custom fabrication is checked and all necessary adjustments are made. (See CMS *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, Quality Standards,* Appendix C. Definition of Terms)

Customization required for each individual patient is also recognized in the definitions of "custom-molded" and "custom-fabricated" in the Texas Orthotics and Prosthetics act. See those

definitions below.[2]

(6) CMS is the Center for Medicare and Medicaid Services located in Baltimore Maryland. CMS is the federal agency within the United States Department of Health and Human Services (hereinafter HHS) which is responsible for management of the Medicare program and oversight of the states' Medicaid programs. CMS is responsible for reviewing and approving, if appropriate, State Medicaid Plans and amendments and arranging for payment of the federal funds to the states and periodic audits to confirm that the states are spending the FFP in accordance with their approved State Medicaid Plans. CMS carries out most Medicare operational activities through contractors that include fiscal intermediaries, regional home health and hospice intermediaries, carriers, and durable medical equipment regional carriers. (http://www.cms.hhs.gov/History/Downloads/CMSInBaltimore.pdf)

(7) HCFA means the federal Health Care Financing Administration established in 1977 to administer and over see the Medicare program and to provide federal oversight of the states' management of their Medicaid programs. HCFA was renamed CMS effective July 1, 2001. (See HCFA in CMS Acronyms glossary at http://www.cms.hhs.gov/apps/acronyms/)

(8) SINGLE STATE AGENCY means an agency within state government designated by the state, as required by 42 U.S.C. § 1396a(5), to be responsible for administration of the state Medicaid program.

(9) HHSC or HEALTH AND HUMAN SERVICES COMMISSION is the agency within Texas government that has been designated as the single state agency responsible for administration of the Medicaid program at the state level.

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[2] See also 42CFR414.224

(10) FISCAL AGENT or CONTRACTORS Medicare and Medicaid contract with companies to provide administrative services including claims processing, auditing, fraud investigation and detection.

(11) TRAILBLAZER HEALTH ENTERPRISES LLC (Trailblazer) administers the Medicare program under contracting arrangements with the Centers for Medicare & Medicaid Services (CMS). As Medicare Administrative Contractor, TrailBlazer administers some aspect of the Medicare program for beneficiaries and providers in virtually every state.

(12) HEALTH INTEGRITY LLC (Health Integrity) is a contractor that performs fraud and abuse detection and investigation for Medicare.

(13) PALMETTO GBA and **NATIONAL SUPPLIER CLEARING HOUSE (NSC)** Palmetto Government Benefits Administrators (Palmetto GBA) and its affiliated company, National Supplier Clearinghouse, administer the Medicare for CMS, and are responsible for, among other things, processing and paying Medicare claims and for enrolling suppliers and issuing and revoking Medicare supplier numbers. Palmetto GBA has been a Medicare contractor since the inception of the Medicare program and provides service throughout the United States and its territories.

(14) TMHP means Texas Medicaid and Health Partnership. TMHP is a coalition of contractors which, since January 1, 2004, has carried out the Medicaid claims payment administrator duties for the State of Texas, under contract with the Texas Health and Human Services Commission (HHSC). TMHP is headed by ACS State Healthcare LLC (based in Atlanta Georgia). Other members of the TMHP are: Accenture (headquarters in Hamilton, Bermuda); Computer Associates (CA) (headquarters in Islandia, NY); Hewlett Packard (HP)

(headquarters in Palo Alto, Calif); Health Management Systems (HMS), Inc.(headquarters in New York, NY) MMC Group (headquarters in Irving TX); and SBC (which has now been acquired by AT&T of New York, NY.).

(15) NHIC or NATIONAL HERITAGE INSURANCE COMPANY is the company which administered Medicaid claims in the State of Texas under contract with the Texas Health and Human Services Commission (HHSC) prior to January 1, 2004.

(16) MEDICARE SUPPLIERS AND MEDICAID PROVIDERS are those individuals and entities who have applied for and been approved to provide medical benefits, items, or services pursuant to the rules of Medicare and the Medicaid programs and who have signed a supplier or provider agreement. There is no significant difference between the terms supplier and provider, and they may be used interchangeably herein. Participation as a supplier with Medicare or as a provider with Medicaid is voluntary. Every person and entity desiring to participate in Medicare as a supplier and every person and entity desiring to participate in Medicaid as a provider, agrees to, and is obligated to know, follow, and abide by, each program's rules, regulations, conditions and limitations, including all revisions, changes and supplements, as well as all applicable federal and state licensure and regulatory requirements.

(17) MEDICARE DMEPOS SUPPLIERS (durable medical equipment, prosthetics, orthotics). Medicare DMEPOS suppliers are entities who have enrolled under special rules and regulations, qualifications and criteria of Medicare and Medicaid to provide durable medical equipment, prosthetics, or orthotics. (Those terms are defined below). DMEPOS suppliers are required to meet certain quality standards and other standards, including but not limited to the obligation to operate their businesses in accordance with all applicable state and federal laws and

regulations. Pursuant to 42 C.F.R. 424.57(c)(1) every DMEPOS supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet various standards, including that it operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements. "Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by the State standards under which the professional is licensed, certified or registered." See CMS *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, Quality Standards* Section I (C)(3). Medicare suppliers who desire to supply durable medical equipment, prosthetics, orthotics must meet and follow the Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges of 42 C.F.R. 424.57. Said suppliers must also certify in their applications for DMEPOS supplier billing privileges that they meet and will continue to meet the application certification standards of 42 C.F.R. 424.57(c). Supplier standards (1) and (2) of said section state that supplier:

> "(1) Operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements;
>
> (2) Has not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change.)";

In addition to meeting the supplier standards cited above, a DMEPOS supplier must meet the following conditions in order to be eligible to receive payment for a Medicare- covered item:

(1) The supplier has submitted a completed application to CMS to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations it uses to furnish Medicare-covered DMEPOS, with the exception of locations that it uses solely as warehouses or repair facilities.) (2) The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges. (CMS issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service. (3) CMS has not revoked or excluded the DMEPOS supplier's privileges during the period which the item was furnished has not been revoked or excluded. (sic) See 42 C.F.R.424.57(b).

(18) TEXAS MEDICAID PROVIDER PROCEDURES MANUAL (often referred to as the Provider Manual) is the book published every year for the Medicaid program. It is available to the public and is provided to enrolled providers. The manual is also available on the internet. Following the parameters of the approved State Plan, the Provider Manual gives providers the Medicaid program rules, regulations, restrictions, conditions, limitations and instructions for providing allowable medical benefits, items, and services. The manuals are divided into sections of general information applicable to every provider type and sections specific and unique to individual provider types. The specific sections in the manual for the various provider types contain the billing instructions and specific statements of what can and cannot be billed to the Medicaid program and often specify the qualifications and credentials required of each person who intends to bill for allowable medical benefits.

(19) MEDICARE SUPPLIER MANUAL is the Medicare counter part to the states' Medicaid providers manuals. It is available on the CMS website and from the website of

Palmetto GBA. Similar to its state counterpart, the Medicare Supplier Manual contains the current Medicare guidelines and medical policies.

(20) BILLS and CLAIMS (often used synonymously) are the written requests for payment submitted by health care providers to Medicare and to Medicaid for allowable medical benefits, items, and services provided and supplied to Medicare and Medicaid beneficiaries. Bills or claims submitted to Medicare and Medicaid must be on a claim form approved by the federal government. All claims from suppliers to Medicare and from providers to Medicaid are submitted through the fiscal agents. Although suppliers and providers may sometimes submit claims in groups for efficiency, every claim is considered individually.

(21) HCFA 1500 or CMS 1500 is the name of the claim form approved by the federal government for use by Medicare and Medicaid providers The form's original name of HFCA 1500 was changed to CMS 1500 after HCFA became known as CMS in 2001. Bills or claims may be submitted on paper 1500 claim forms or an electronic equivalent.

(22) HEALTH CARE PROCEDURE CODING SYSTEM ("HCPCS") (pronounced "hick-picks") is a standardized coding system for describing and identifying health care services and supplies. HCPCS was developed, and is maintained, by the federal government to provide a uniform language that accurately describes the specific medical services and items delivered to a patient, and in many cases, the qualifications of the person providing the services. Each year in the United States, health care insurers process over 5 billion claims for payment. For Medicare and other health insurance programs to ensure that these claims are processed in an orderly and consistent manner, standardized coding systems are essential. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR Sec. 414.40 (a) require CMS to adopt

standards for coding systems that are used for reporting health care transactions. The HCPCS Level II Code Set is one of the standard code sets used for this purpose. Providers billing Medicare/Medicaid ***must*** use the applicable HCPCS billing code to describe every medical service and item they claim to have provided. (http://www.cms.hhs.gov/MEdHCPCSGenInfo/).

(23) PROVIDER NUMBER means the unique identification number assigned to health care providers by the Medicare and Medicaid. Prior to May 23, 2008 the provider number in the Texas Medicaid program was called the Texas Provider Identifier (TPI). As of May 23, 2008 use of the unique National Provider Identifier (NPI) assigned to all health care providers by the National Provider System became mandatory on claims submitted to all health plans. NPI is a Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard. The NPI is a unique identification number for covered health care providers. Covered health care providers and all health plans and health care clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA. Such numbers are used by health care providers to identify themselves in their billings and other transactions.

(24) R.A. AND R&S mean Remittance Advice and Remittance & Status Report. They are the written explanations and reports sent to providers by Medicaid and Medicare to confirm receipt of and document claims submitted by the providers and to report the status of the claims processing and payment. After a claim has been received and processed, Medicaid and/or Medicare contractors produce the RA, which may serve as a companion to a claim payment(s) or as an explanation when there is no payment. The RA explains the reimbursement decisions including the reasons for payments and adjustments of processed claims. Providers use the RA to post payments and to review claim adjustments. The RA also contains detailed and specific

claim decision information.

(25) CLAIM NUMBER is a series of numbers and/or letters assigned by Medicaid to every bill or claim submitted by a provider. The numerical sequence provides information about each claim such as the date of receipt of the claim and the media by which it was transmitted. Medicaid also calls its claim numbers the Internal Control Number or ICN.

(26) TBOP means the Texas Board of Orthotics and Prosthetics which was created as part of the Texas Orthotics and Prosthetics Act (Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999) and is found in Title 3, Chapter 605 of the Texas Occupations Code. The TBOP is responsible for administering and regulating the practice of orthotics and prosthetics in the State of Texas as required by the Texas Orthotics and Prosthetics Act. The Board is responsible for issuing, suspending, denying, and revoking licenses as well as rule making and overall enforcement of the Texas Orthotics and Prosthetics Act.

(27) DURABLE MEDICAL EQUIPMENT is a term used to describe certain medical equipment used in the home, and included such things as includes iron lungs, oxygen tents, hospital beds, infusion pumps, blood-testing strips and blood glucose monitors for individuals with diabetes and wheelchairs. (See 42 U.S.C. § 1395x(n))

(28) DMEPOS means durable medical equipment, prosthetics, orthotics.

(29) ORTHOTICS means the science and practice of measuring, designing, fabricating, assembling, fitting, adjusting, or servicing an orthosis under an order from a licensed physician, chiropractor, or podiatrist for the correction or alleviation of neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity. (See: Texas Administrative Code §821.2 (27), and the Texas Occupations Code Title 3 Chapter 605 (The Texas Orthotics and Prosthetics Act),

Sec. 605.002(14)).

(30) ORTHOSIS means a *custom-fabricated* or *custom-fitted* medical device designed to provide for the support, alignment, prevention, or correction of neuromuscular or musculoskeletal disease, injury, or deformity. The term does not include a fabric or elastic support, corset, arch support, low-temperature plastic splint, a truss, elastic hose, cane, crutch, soft cervical collar, orthosis for diagnostic or evaluation purposes, dental appliance, or other similar device carried in stock and sold by a drugstore, department store, or corset shop. (See Texas Administrative Code §821.2 (25), and the Texas Occupations Code Title 3 Chapter 605 (The Texas Orthotics and Prosthetics Act), Sec 605.002(12)).

(31) CUSTOM FABRICATED custom fabricated item is one that is individually made for a specific patient. No other patient would be able to use this item. A custom fabricated item is a device which is fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as x-rays) of the body part. The fabrication may involve using calculations, templates and components. This process requires the use of basic materials including, but not limited to plastic, metal, leather or cloth in the form of uncut or unshaped sheets, bars, or other basic forms and involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling and finishing prior to fitting on the patient. (See CMS *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, Quality Standards,* Appendix C. Definition of Terms; Texas Administrative Code §821.2 (9); and the Texas Occupations Code Title 3 Chapter 605 (The Texas Orthotics and Prosthetics Act), Sec 605.002(3)).

(32) CUSTOM-FITTED a custom fitted item is a prefabricated device, which is manufactured in quantity without a specific patient in mind and then, pursuant to a prescription, is adjusted, fitted, and aligned for a specific individual according to sound biomechanical principles. The device may or may not be supplied as a kit that requires some assembly and/or fitting and adjustment, or a device that must be trimmed, bent, molded (with or without heat), or otherwise modified by an individual with expertise in customizing the item to fit. (See CMS *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, Quality Standards,* Appendix C. Definition of Terms; the Texas Administrative Code §821.2 (10); and the Texas Occupations Code Title 3 Chapter 605 (The Texas Orthotics and Prosthetics Act), Sec 605.002(4)).

(33) PROSTHESIS means a custom-fabricated or fitted medical device that is not surgically implanted and is used to replace a missing limb, appendage, or other external human body part, including an artificial limb, hand, or foot. The term does not include an artificial eye, ear, finger, or toe, a dental appliance, a cosmetic device, including an artificial breast, eyelash, or wig, or other device that does not have a significant impact on the musculoskeletal functions of the body. See CMS *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, Quality Standards,* Appendix C. Definition of Terms, and Texas Administrative Code §821.2 (32), and the Texas Occupations Code Title 3 Chapter 605 (The Texas Orthotics and Prosthetics Act), Sec. 605.002(17)).

(34) PROSTHETICS means the science and practice of measuring, designing, fabricating, assembling, fitting, adjusting, or servicing a prosthesis under an order from a licensed physician, chiropractor, or podiatrist. (See Texas Administrative Code §821.2 (33), and the Texas

Occupations Code Title 3 Chapter 605 (The Texas Orthotics and Prosthetics Act), Sec. 605.002(18)).

(35) LICENSED ORTHOTIST (LO) means a person licensed under the Texas Administrative Code who practices orthotics and represents the person to the public by a title or description of services that includes the term "orthotics," "orthotist," "brace," "orthosis," "orthoses," "orthotic," or a similar title or description of services. (See Texas Administrative Code §821.2 (18), and the Texas Occupations Code Title 3 Chapter 605 (The Texas Orthotics and Prosthetics Act), Sec. 605.002(6)).

(36) LICENSE means a license, registration, certificate, accreditation, or other authorization issued under the Texas Administrative Code to engage in an activity regulated under the code. (See Texas Administrative Code §821.2 (17).

(37) ORTHOTIC FACILITY means a physical site, including a building or office, where the orthotic profession and practice normally take place. (See Texas Administrative Code §821.2 (26), and the Texas Occupations Code Title 3 Chapter 605 (The Texas Orthotics and Prosthetics Act), Sec. 605.002(13)).

(38) ORTHOTIST IN CHARGE means an orthotist who is designated on the application for accreditation as the one who has the authority and responsibility for the facility's compliance with the Act and rules concerning the orthotic practice in the facility. (See Texas Administrative Code §821.2 (28).

(39) PRACTITIONER means a person licensed under the Orthotics and Prosthetics Act,

(Texas Occupations Code, Chapter 605) or the Texas Administrative Code as a prosthetist, orthotist, or prosthetist/orthotist. (See Texas Administrative Code §821.2 (30).

(40) PROSTHETIC/ORTHOTIC FACILITY means a physical site, including a building or office, where the prosthetic and orthotic professions and practices normally take place. (See Texas Administrative Code §821.2 (35).

(41) PROSTHETIST IN CHARGE--A prosthetist who is designated on the application for accreditation as the one who has the authority and responsibility for the facility's compliance with the Act and rules concerning the practice of prosthetics in the facility. (See Texas Administrative Code §821.2 (36).

(42) PROSTHETIST/ORTHOTIST IN CHARGE--A prosthetist/orthotist who is designated on the application for accreditation as the one who has the authority and responsibility for the facility's compliance with the Act and rules concerning the practice of prosthetics and orthotics in the facility. (See Texas Administrative Code §821.2 (37).

(43) PROFESSION OF PROSTHETICS OR ORTHOTICS – Means allied health care medical services used to identify, prevent, correct, or alleviate acute or chronic neuromuscular or musculoskeletal dysfunctions of the human body that support and provide rehabilitative health care services concerned with the restoration of function, prevention, or progression of disabilities resulting from disease, injury, or congenital anomalies. Orthotic and prosthetic services include direct patient care, including consultation, evaluation, treatment, education, and advice to maximize the rehabilitation potential of disabled individuals. (See Texas Administrative Code §821.2 (31),and the Texas Occupations Code Title 3 Chapter 605 (The Texas Orthotics and

Prosthetics Act), Sec. 605.002(16)).

(44) DMEPOS SUPPLIERS are the entities who have enrolled under special rules and regulations, qualifications and criteria of Medicare and Medicaid to provide durable medical equipment, prosthetics, or orthotics**.** DMEPOS suppliers are required to meet certain quality standards and other standards, including but not limited to the obligation to operate their businesses in accordance with all applicable state and federal laws and regulations Pursuant to 42 CFR 424.57(c)(1) every DMEPOS supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet various standards, including that it operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements. "Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by the State standards under which the professional is licensed, certified or registered."
(See CMS *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, Quality Standards Section I (C)(3)).*

TEXAS LAWS REGARDING LICENSING OF ORTHOTIST and ACCREDITING OF ORTHOTIC FACILITIES

(1) LICENSE REQUIRED: **Sec. 605.251 of the Texas Orthotics and Prosthetics Act**

Since September 1, 1999 Texas has required a state license to practice or attempt to practice orthotics in the state. Sec. 605.251 of the Texas Orthotics and Prosthetics Act states:

> "LICENSE REQUIRED. A person may not practice, attempt to practice, or offer to practice orthotics or prosthetics, act as an assistant to a person who practices orthotics or prosthetics, or in any way hold the person out as being able to practice orthotics or

prosthetics unless the person holds a license issued by the board [TBOP] under this chapter." (Texas Orthotics and Prosthetics Act (Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999; Texas Occupations Code Title 3 Chapter 605)).

(2) PRACTICE LOCATION LIMITATION: Texas Administrative Code §821.29(a)(1)

Since November 8, 1998 the laws of the State of Texas have required that a person licensed under the Texas Orthotics and Prosthetics Act, (Act), Texas Occupations Code, Chapter 605, who practices in Texas shall practice only in facilities accredited under the Act, unless the type of practice is exempted by the Act, §§605.301 - 605.305, or the facility is exempted by the Act, §605.260(e). (Texas Administrative Code, Title 22, Part 37, Chapter 821, Rule §821.29(a)(1))

(3) EXEMPTIONS TO PRACTICE LOCATION LIMITATION

None of the types of practices or facilities listed in the Texas Administrative Code §821.29(a)(1) as exemptions to the requirement that orthotics only be practiced in accredited facilities have any application to any of the defendants in this case. The facilities exempted by the Act, §605.260(e) are discussed in paragraph 4 below. The types of practices exempted from by the Act §§605.301 - 605.305 and the facilities exempted by the act are as follows:

(A) Sec. 605.301 of the Act: Persons licensed by state agencies (other than the TBOP) to perform health care services are not covered by the Texas Orthotics and Prosthetics Act under specific circumstances. Section 605.301 of the Act provides that:

> "This chapter does not restrict a person who holds a license issued by another state agency from performing health care services within the scope of the license holder's applicable licensing act if the license holder:

(1) practices in conformance with the applicable laws and rules relating to the person's license; and

(2) does not:

(A) violate Section 605.251 [practicing, attempting to practice, or offering to practice orthotics without a license];

(B) represent to others that the license holder practices orthotics or prosthetics; or

(C) use the terms "prosthetist," "prosthesis," "prosthetic," "artificial limb," "orthotist," "orthosis," "orthotic," or "brace" or the letters "LP," "LPA," "LO," "LOA," "LPO," or "LPOA" **or any derivative of those terms or letters in connection with the license holder's name or practice."** (Emphasis added)

(B) Sec. 605.302 of the Act: Students in orthotics or prosthetics Section 605.302 of the Act provides that:

"This chapter does not apply to the activities and services of a student in orthotics or prosthetics who is:

(1) pursuing a course of study in:

(A) an orthotic or prosthetic program at a college or university recognized and accredited by the Commission on Accreditation of Allied Health Education Programs; or

(B) an orthotic or prosthetic education program having education standards that are equivalent to or exceed the standards adopted by the Commission on Accreditation of Allied Health Education Programs; or

(2) working in a recognized training center or research facility, if the activities and services provided by the person at the training center or research facility constitute a part of the person's course of study in the discipline in which the person's supervisor is licensed under this chapter."

(C) Sec. 605.303 of the Act: Certain license holders. Section 605.303 of the Act provides that:

"This chapter does not apply to:

(1) a podiatrist practicing under Chapter 202;

(2) a chiropractor practicing under Chapter 201;

(3) an occupational therapist practicing under Chapter 454; or

(4) a physical therapist practicing under Chapter 453."

(D) Sec. 605.304 of the Act: Pedorthists. Section 605.304 of the Act provides:

"(a) In this section:

(1) "Certified pedorthist" means a person certified by the Board for Certification in Pedorthics in the design, manufacture, fit, and modification of shoes and related foot orthoses below the anatomical ankle joint as prescribed by a licensed doctor of medicine or a doctor of podiatry for the amelioration of a painful or disabling condition of the foot; and

(2) "Foot orthosis" includes prosthetic toe fillers or orthoses for use below the ankle.

(b) This chapter does not apply to a certified pedorthist."

(E) Sec. 605.305 of the Act: Pharmacist. Section 605.305 of the Act provides:

"A pharmacist licensed by the Texas State Board of Pharmacy or a person who is working under the direct supervision of a pharmacist may practice orthotics. This chapter does not preclude a pharmacist from being reimbursed by a state-funded program for providing orthotic services."

(4) EXEMPT FACILITIES Sec. 605.260(e)

Section 605.260(e) provides that:

"This section does not apply to a facility licensed under Subtitle B, Title 4, Health and Safety Code."

The facilities required to be licensed under Subtitle B, Title 4, Health and Safety Code

are:

(a) Chapter 241. Hospitals;

(b) Chapter 242. Convalescent and Nursing Homes and Related Institutions;

(c) Chapter 243. Ambulatory Surgical Centers;

(d) Chapter 244. Birthing Centers

(e) Chapter 245. Abortion Facilities;

(f) Chapter 246. Continuing Care Facilities (Facilities which furnish a living unit, together with personal care services, nursing services, medical services, or other health-related services, under an agreement "Continuing care contract" that requires the payment of an entrance fee by or on behalf of a resident in exchange for the furnishing of continuing care by a provider and that is effective for: (A) the life of the resident; or (B) more than one year);

(g) Chapter 247. Assisted Living Facilities;

(h) Chapter 248. Special Care Facilities (Institutions or establishments that provides a continuum of nursing or medical care or services primarily to persons with acquired immune deficiency syndrome or other terminal illnesses. The term includes a special residential care facility);.

(I) Chapter 249. Maternity Homes

(j) Chapter 251. End Stage Renal Disease Facilities; and

(k) Chapter 252. Intermediate Care Facilities for the Mentally Retarded.

(5) ACCREDITATION OF ORTHOTIC FACILITIES

The Texas Orthotics and Prosthetic Act mandates in Section 605.260(a) that the TBOP set rules which shall establish requirements for the accreditation and the renewal of an accreditation of an orthotic or prosthetic facility in which orthotics or prosthetics are conducted; and in 605.260(c) that an orthotic or prosthetic facility must be under the on-site direction of an orthotist or prosthetist licensed by the board in the discipline for which accreditation is sought.

The accreditation rules established by the TBOP took effect on November 8, 1998. Those rules mandate that, except for the entities exempted from the Texas Orthotics and Prosthetics act which are listed in paragraph 4 above, every other facility (including OSDME) which holds itself out as an orthotic facility or where person(s) providing health care services at the facility hold themselves out as performing or offering to perform prosthetics and/or orthotics as defined in the Act must be accredited by the TBOP. See Texas Administrative Code, Title 22, Part 37, Chapter 821, Rule §821.29. Various provisions of that rule provide as follows:

(a) **Purpose of facility accreditation.** "The purpose of accreditation is to identify for prospective patients, referral sources, and third-party payers which prosthetic and/or orthotic facilities meet the board's requirements. This section is adopted under the Act, §605.260. All facilities where orthotics and prosthetics are provided by persons licensed or registered under this title must be accredited under these rules, unless the facility is exempted under the Act, §605.260(e)." (Rule §821.29(b)).

(b) **Accreditation application.** Accreditation applications must include among other things:

(1) "the name and Texas license number of the orthotist, or prosthetist/orthotist who is designated as the on-site practitioner in charge and his or her notarized signature. If the on-site practitioner in charge is in charge of more than one facility, a list of all facilities at which the practitioner is in charge and a work schedule for the practitioner in charge must be included." (Rule §821.29(c)(1)(H)); and

(2) "the signature of the on-site practitioner(s) in charge of the facility" (Rule §821.29(c)(1)(K)).

(c) **Requirements for accredited facilities**. Accreditation requires among other things:

(1) Prosthetic and/or orthotic facilities must apply for accreditation with the board and pay an accreditation fee within 60 days of the first patient treatment date, whichever is later.

(2) An accredited facility must be under the clinical on-site direction of a prosthetist, orthotist, or prosthetist/orthotist licensed by the board in the discipline in which the facility sought accreditation. The person shall supervise the provision of prosthetics or orthotics in accordance with the Act and rules and shall be considered the person in charge. To change the designation of the on-site practitioner(s) in charge, the facility shall notify the board in writing of the name and license number of the new on-site practitioner(s) and the date the effective date of the change. The written notice shall be accompanied by the appropriate fee as set out in § 821.5 of this title (relating to Fees). The notice and fee shall be submitted to the board before the change is effective;

(3) A facility accredited under the Act is required to comply with the Act and rules of the board at all times.

(4) An accredited facility is required to report to the board any change regarding the on-site prosthetist, orthotist, or prosthetist/orthotist who is

clinically directing the facility before the change is effective.

(d) **Definition of Orthotist in charge**. TBOP's rules define orthotist in charge as: "An orthotist who is designated on the application for accreditation as the one who has the authority and responsibility for the facility's compliance with the Act and rules concerning the orthotic practice in the facility. §821.29(e)(2),(5),(6), (8), and §821.2(28)

(The government will offer evidence that the "orthotist in charge" is also sometimes referred to as the"on-site practitioner", the "on-site practitioner in charge", the "practitioner in charge", or simply the "PIC").